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New Rules for Health Care Procurement in the UK. A Critical Assessment from the Perspective of EU Economic Law¹

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Abstract

The recently adopted *UK National Health Service (Procurement, Patient Choice and Competition) (No. 2) Regulations 2013* include an interesting and somehow unsettling provision authorising anti-competitive behaviour in the commissioning of health care services by the National Health Service (NHS), if that is in the best interest of health care users. Generally, it seems that under the new public procurement and competition rules applicable to the NHS, whatever is considered to be in the “interest of patients” could trump pro-competitive requirements and allow the commissioning entity to engage in distortions of competition. Such distortions could either take place directly, or by the NHS commissioners’ facilitation of anti-competitive behaviour by tenderers and service providers. And they could be accepted as long as a sort of qualitative cost-benefit analysis shows that net advantages are derived from the anti-competitive procurement activity. The apparent oddity of such general “authorisation” for public buyers to engage in anti-competitive procurement of health care services deserves some careful analysis, which this paper carries out.

The paper assesses Regulation 10 of the *NHS Procurement, Patient Choice and Competition Regulations 2013* and the substantive guidance published by the UK’s health care sector regulator (Monitor) from the perspective of EU economic law. More specifically, Regulation 10 is assessed in connection to EU public procurement and competition rules. The paper claims that there is a *prima facie* potential incompatibility between Regulation 10 of the *2013 NHS Procurement, Patient Choice and Competition Regulations* and both EU competition law and public procurement law—which are, in principle, opposed to any anti-competitive or competition restrictive behaviour in the conduct of public procurement activities. Consequently, there is a need for an EU law compliant, restrictive interpretation and enforcement of the provision—at least where there is a cross border effect on competition and/or a cross border interest in tendering for the health care contracts, which triggers the application of both EU competition law and public procurement law.

1. Introduction

The UK is engaged in a wide strategy for the reform of its public sector and, more specifically, for the implementation of significant changes in the modes of provision of public services. This reform particularly affects the UK’s health care system.³ Generally, as spelled out in the 2011 *Open Public Services White Paper*,⁴ the reform

¹ I am thankful to Prof. Erika Szyszczak for the discussions on this topic while preparing another paper on which this one is partially built. I am also thankful to an anonymous reviewer, to my colleagues at the School of Law of the University of Leicester, Dr Jule Mulder and Dr Sebastian Peyer, and to Mr Ignacio Herrera Anchustegui from the University of Bergen Center for Competition Law and Economics, for their comments and suggestions, both in conversation and in view of earlier drafts. The standard disclaimer applies.

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⁴ HM Government, *Open Public Services White Paper*, July 2011, available at <http://files.openpublicservices.cabinetoffice.gov.uk/OpenPublicServices-WhitePaper.pdf> [Accessed July 8, 2014]. Also, *Choice and Competition: Delivering Real Choice—A report from the NHS Future Forum* (2011), available at https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/213749/dh_127541.pdf [Accessed July 8, 2014]. For discussion, see J Davies “Changes and Challenges in UK Social Services: Social Services of General Interest or “Welfare” Services of General Economic Interest?”, in U Neergaard et al (eds), *Social Services of General Interest in the EU, Legal Issues of Services of General Interest* (The Hague: Springer, TMC Asser Press, 2013) pp. 513-540. See also ACL Davies “This Time It’s for Real: The Health and Social Care Act 2012” (2013) 76(3) *Modern Law Review* 564.

seeks to promote competition amongst an increasingly diverse base of private, public and non-profit providers of public services, with the ultimate aim of raising the standards of the provision and reducing its costs. However, in some areas of the public sector, the need to carry out the reform while maintaining competitive markets may be limited by a political preference for other policy goals. This is particularly true in the area of social services or non-economic services of general interest, as the recent reform of the EU public procurement rules indicates (below §4).

In the specific case of the health care system, the UK has enacted a controversial provision regarding the commissioning activities of the National Health Service (NHS). Apparently, a concept of “patients’ interest” can trump competition law considerations and pro-competitive public procurement requirements, as long as a sort of qualitative cost/benefit analysis indicates that the “net” result of the anti-competitive public sector activity is positive in terms of the needs of the users of the service. Specifically, the recently adopted *UK National Health Service (Procurement, Patient Choice and Competition) (No. 2) Regulations 2013* (hereinafter, the NHS Procurement, Patient Choice and Competition Regulations 2013)⁵ include a provision authorising anti-competitive behaviour in the commissioning of NHS services, as long as it is in the interest of health care users. According to Regulation No 10:

10.—(1) When commissioning health care services for the purposes of the NHS, a relevant body must not engage in anti-competitive behaviour [ie behaviour which would (or would be likely to) prevent, restrict or distort competition], unless to do so is in the interests of people who use health care services for the purposes of the NHS which may include—

(a) by the services being provided in an integrated way (including with other health care services, health-related services, or social care services); or

(b) by co-operation between the persons who provide the services in order to improve the quality of the services.

(2) An arrangement for the provision of health care services for the purposes of the NHS must not include any term or condition restricting competition which is not necessary for the attainment of—

(a) intended outcomes which are beneficial for people who use such services; or

(b) the objective referred to in regulation 2 [ie securing the needs of the people who use the services, improving the quality of the services, and improving efficiency in the provision of the services] (emphasis added).

The only illumination provided in the Explanatory Memorandum of the *NHS Procurement, Patient Choice and Competition Regulations 2013* is that:

*‘The Regulations place further requirements on commissioners to ensure accountability and transparency in their expenditure. In particular: [...] not to engage in anti-competitive behaviour unless to do so is in the interest of patients. Regulation 10 makes clear that behaviour in the interests of patients may include services being provided in an integrated way or co-operation between providers in order to improve the quality of services. This reflects the **Government’s firm view that competition is a means to improving services and not an end in itself**’.*⁶

Generally, then, it seems that under the new NHS public procurement rules, whatever is considered in the “interest of patients” could trump pro-competitive requirements and allow the commissioning entity to engage in distortions of competition. That would create a risk of incompatibility of this provision with EU competition law as such legal authorisation may clash and be superseded by the general prohibition of anti-competitive agreements in Article 101(1) of the Treaty on Functioning of the European Union (TFEU).⁷ Such incompatibility could only be avoided if “patients’ interest” could be reconciled with “consumer-benefitting (qualitative) efficiencies” under the exception provided for by Article 101(3) TFEU. If such reconciliation was not possible, the blanket authorisation for a

⁵ 2013 No. 500, entering into force on 1 April 2013. It is important to bear in mind that the National Health Service (Procurement, Patient Choice and Competition) (No 2) Regulations 2013 (SI. 2013 No.500), which were made on 6 March 2013, replace the National Health Service (Procurement, Patient Choice and Competition) Regulations 2013 (SI. 2013 No.257), which were made on 11 February 2013. The Regulations were made pursuant to sections 75, 76, 77 and 304(9) and (10) of the Health and Social Care Act 2012. For discussion on some of the background that led to the adoption of two almost consecutive sets of Regulations, see L Goulding “Is the NHS subject to competition law?”, *EutopiaLaw*, July 19, 2013 available at <http://eutopialaw.com/2013/07/19/is-the-nhs-subject-to-competition-law/> [Accessed July 8, 2014]. See also S Smith, D Owens and E Heard, “New procurement legislation for English Healthcare Bodies—The National Health Service (Procurement, Patient Choice and Competition) (No.2) Regulations 2013” (2013) 22 P.P.L.R. NA109.

⁶ Explanatory Memorandum, NHS Procurement, Patient Choice and Competition Regulations 2013, para. 7.4, emphasis added.

⁷ Consolidated version. [2012] OJ C326/1. Issues of compatibility with other EU competition law rules and, particularly, State aid controls are not covered in this paper. For discussion, see V Hatzopoulos, “Public procurement and state aid in national health care systems”, in E Mossialos *et al* (eds), *Health Systems Governance in Europe. The Role of European Union Law and Policy* (Cambridge: Cambridge University Press, 2010) pp. 381-420.

restriction of competition in the health care public procurement setting provided for by Regulation 10 would be extremely troubling and clearly opposed to EU economic law.

However, the overall authorisation to engage in anti-competitive commissioning or procurement in Regulation 10 of the *NHS Procurement, Patient Choice and Competition Regulations 2013* may seem broader than it actually can be constructed, as instances of clearly detrimental anticompetitive procurement should be rare and not actually susceptible to legal authorisation. To begin with, joint/integrated provision or collaboration aimed at improving the quality of the health services may not constitute instances of illegal anticompetitive behaviour [and, therefore, not breach Article 101(1) TFEU]. Secondly, even competition-restrictive procurement decisions may still be subject to a general legal exception or authorisation if they provide significant net positive effects [and, therefore, covered by Article 101(3) TFEU]. So, in the end, instances of detrimental competition restrictions in the patient's interest should be residual and, only in those cases, hard to make compatible with EU economic law's requirements.⁸ Therefore, the analysis will need to determine to what extent Regulation 10 can be reconciled with Article 101(1) and 101(3) TFEU and their enforcement, particularly by adopting a strict interpretation of what constitutes a (superior) "patients' interest" that can trump competition considerations, as advocated later (§3).

That notwithstanding, and even if Regulation 10(2) sets a clear proportionality requirement,⁹ the general impression remains that due to its open-ended drafting this "anti-competitive authorisation" may also be at odds with the general requirements of EU public procurement law. More specifically, with the principle of competition embedded in Article 18 of the new Directive 2014/24¹⁰ (further discussed below §4), so that the application of Regulation 10(1) for contracts of cross-border interest covered by EU law may result in a breach of that Directive. However, as will also be assessed, the new EU public procurement Directive creates a light-touch approach to the procurement of social services and allows contracting entities commissioning health care services to take into account qualitative considerations and the needs of different categories of vulnerable users [such as those patients requiring long-term or intense care; Article 76(2) Directive 2014/24]. Therefore, the apparent incompatibility between Regulation 10 of the *NHS Procurement, Patient Choice and Competition Regulations 2013* and the EU public procurement rules will also depend on the possibility to reconcile their interpretations.

It is important to stress that if any of these two potential conflicts materialised,¹¹ the application of the *NHS Procurement, Patient Choice and Competition Regulations 2013* would result in breaches of EU law. Such breaches could give rise to an investigation by the European Commission under Article 258 TFEU and eventually lead to the imposition by the Court of Justice of the European Union (CJEU) of the fines regulated in Article 260 TFEU. The infringements may be particularly serious if they resulted in a general and persistent infringement of EU public procurement and competition law.¹² Equally, specific decisions adopted under Regulation 10 of the *NHS Procurement, Patient Choice and Competition Regulations 2013* by Monitor, or prior decisions adopted by NHS commissioners, may be open to judicial review and eventually trigger references for preliminary rulings to the CJEU under Article 267 TFEU. All such litigation would be undesirable and should be avoided, particularly if the apparent contradiction between Regulation 10 of the *NHS Procurement, Patient Choice and Competition Regulations 2013* and EU public procurement and competition law can be overcome by means of standard interpretation and sensible enforcement.

Therefore, the scope, interpretation and limits of Regulation 10 of the *NHS Procurement, Patient Choice and Competition Regulations 2013* deserve a critical appraisal from the perspective of EU economic law. This paper will explore each of these issues in turn in the following sections, which are respectively concerned with the scope, anticipated interpretation and enforcement of Regulation 10 by Monitor (§2), and its compatibility with EU competition law (§3) and EU public procurement law (§4). Some conclusions will summarise the findings (§5).

2. Scope and interpretation of Regulation 10

2.1. The role of Monitor and its 2013 Substantive guidance

⁸ The reasoning applies, more generally, to the UK's domestic competition rules as well.

⁹ The proportionality requirement should avoid excesses in the authorisation of net detrimental anti-competitive procurement apparently in the patients' interest.

¹⁰ Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement and repealing Directive 2004/18/EC [2014] OJ L94/65.

¹¹ *ie* if Regulation 10 could not be reconciled with either Article 101(1) and 101(3) TFEU or with Articles 18 and 76(2) of the new public procurement Directive 2014/24.

¹² For discussion on this relatively new approach to the enforcement of EU competition and public procurement law by the European Commission, see P Wennerås "A New Dawn for Commission Enforcement under Articles 226 and 228 EC: General and Persistent (GAP) Infringements, Lump Sums and Penalty Payments" (2006) 43(1) *C.M.L.Rev* 31.

As mentioned in passing, the open-ended and controversial nature of Regulation 10 of the *NHS Procurement, Patient Choice and Competition Regulations 2013* has prompted Monitor¹³ to issue some guidance concerning the scope and interpretation of the authorisation to engage in anticompetitive commissioning or procurement in the pursuit or protection of patients' interest. In its December 2013 *Substantive guidance on the Procurement, Patient Choice and Competition Regulations*,¹⁴ Monitor has spelled-out its interpretation of the general procurement objectives in the *NHS Procurement, Patient Choice and Competition Regulations 2013* and has offered significant guidelines as to the interpretation and intended enforcement of Regulation 10.

As a matter of general approach, Monitor makes it clear that the new regulations are designed to ensure that the NHS procures high quality and efficient health care services that meet the needs of patients and protect patient choice, and that they also prohibit NHS commissioners from engaging in anti-competitive behaviour unless this is in the interests of health care service users or "patients' interest". Moreover, it is important to stress that Regulation 10 serves as a basis for *ex officio* investigations into anti-competitive procurement by Monitor, whereas it can only act on a complaints basis when other Regulations may have been breached. Therefore, Regulation 10 clearly adopts a prominent role in the competition law-related functions assigned to Monitor by the *Health and Social Care Act 2012*—which are clearly guided by the concepts of integrated care, competition and choice.¹⁵

In this regard, it is important to point out that "patients' interest" seems to encompass the necessarily nebulous balance of those three elements (*ie* integrated care, competition and choice) in search of the best clinical results and patients' experience. Consequently, the references to "anti-competitive behaviour in the patients' interest" can be read as instances where some other of the constituents of that complex interest may trump strict competition and choice considerations. In line with this, Monitor's focus on integrated care derives from the need to ensure the seamless, well-coordinated and uninterrupted provision of health care services, particularly to patients affected by complex diseases or that require substantial and long-term care.¹⁶ Consequently, it seems clear that "patients' interest" should be interpreted in a qualitative manner from the start, and that it should be mainly led by medical / clinical considerations, rather than by economic, financial or strictly organisational drivers. It must be acknowledged that such understanding of "patient's interest" will result in difficult balancing exercises between competing goals forming part of the concept of integrated care,¹⁷ as the elements to be taken into consideration are of a different nature. Consequently, the additional guidance provided by Monitor on how to conduct such balancing exercises will be of the utmost relevance.¹⁸

2.2. Coordination with general competition law enforcement in the UK

It is important to stress that the issues discussed above exceed the strict sectoral-approach of the activities of Monitor. In a recent speech on *Competition in Public Services*,¹⁹ the Chief Executive of the Office of Fair Trading (OFT, one of the predecessors of the newly-created Competition and Markets Commission) expressly mentioned the need to address market design issues in the current reform of the provision of public services and, more specifically, in health care services. It is worth noting that the OFT considers that:

Market design needs to flow from the public policy objectives intended from opening up a market. For example, in health it has been considered necessary to fix price tariffs and allow competition to focus on quality to avoid competition focusing on price at the expense of quality. In this context, quality is partly about clinical outcomes, partly about other things like access and service. But articulating clear objectives can be difficult when the purpose of introducing choice and competition itself varies: sometimes to

¹³ The Health and Social Care Act 2012 (2012, Chapter 7) made Monitor the sector regulator for health care services in England and gave it a responsibility for enforcing rules on procurement, patient choice and competition. Monitor's activities are publicised via its webpage: <http://www.monitor.gov.uk/> [Accessed July 8, 2014].

¹⁴ Monitor, *Substantive guidance on the Procurement, Patient Choice and Competition Regulations*, 19 December 2013, available at <http://www.monitor-nhsft.gov.uk/s75> [Accessed July 8, 2014] (hereinafter, Monitor's Substantive Guidance 2013). For an interesting comment, see P Henty, "Monitor guidance on the NHS Procurement, Patient Choice and Competition Regulations 2013" (2014) 23 P.P.L.R. NA84.

¹⁵ As interpreted in section 2.3.3 of *Monitor's Substantive Guidance 2013* (above n 14).

¹⁶ See *Monitor's Substantive Guidance 2013* (above n 14) pp. 32-34.

¹⁷ Mainly, the balance or competing demands will be between 'strict' competition and choice considerations on the one hand, and qualitative dimensions of the provision of health care services on the other.

¹⁸ For discussion, see D Fornaciari "Quality Health Care in the European Union Thanks to Competition Law" (2010) *International Journal of Environmental Research and Public Health* 1. For a more general review of the literature, see M Gaynor "What Do We Know About Competition and Quality in Health Care Markets?" (2006) *NBER Working Paper No. 12301*, available at <http://www.nber.org/papers/w12301> [Accessed July 8, 2014].

¹⁹ C Maxwell, Office of Fair Trading (OFT), "Competition in public services" May 23, 2013, available at http://www.offt.gov.uk/shared_offt/speeches/2013/06-13_Competition_in_public1.pdf [Accessed July 8, 2014].

address concerns about quality, choice or innovation; in others to reduce costs. Weighing up these points is an important first step in market design (emphasis added).

As should be expected, it appears that the approach of the OFT to the reform of health care provision is based on the premise that competition is still the best mechanism to achieve the desirable levels of quality. However, this may seem difficult to reconcile with the provisions of the *NHS Procurement, Patient Choice and Competition Regulations 2013*, which precisely allow NHS commissioners to engage in anti-competitive behaviour in order to achieve desired quality improvements. With this in mind, it will be necessary to ensure that the substantive guidance given by the sectoral regulator Monitor is aligned with the warning issued by the OFT, which will seek direct enforcement of the competition provisions in the health care sector where appropriate, as its recent enforcement track record shows:

*For example, last summer we secured voluntary assurances from eight NHS Hospital Trusts that they will no longer exchange commercially sensitive information about their Private Patient Unit (PPU) prices, to ensure they comply with competition law. We have urged all Trusts to take steps to ensure compliance with competition law when engaging in commercial activity.*²⁰

One can wonder whether this type of enforcement activity will still be possible when NHS commissioners argue that the anti-competitive behaviour of health care providers is justified on the basis of Regulation 10(1) of the *NHS Procurement, Patient Choice and Competition Regulations 2013*, since it was carried out in the “patients’ interest”, measured in qualitative terms. This will offer valuable insights and potential lessons to be learnt by other enforcement agencies when they try to balance economic and non-economic considerations related to competition enforcement in the health care sector (an issue further discussed below §3).

As should have transpired from this initial overview, the enforcement of competition law in this area is growing more and more complicated precisely at a moment where the reform of the provision of public services may have a significant impact on market structure and competitive dynamics. Therefore, it is to be welcome that the OFT has prioritised this area in its strategic plan for 2013-14²¹ and that this focus is likely to gain equally important strategic relevance for the Competition and Markets Authority in the future.²² However, closer coordination with the sectoral regulator Monitor may be necessary at this point in order to prevent sending mixed messages to the actors in the field and, more importantly, to prevent situations where an excessively broad interpretation of regulatory exclusions of competition could take place, particularly if Monitor is the acting competition authority. The market structure resulting from the current wave of public sector reform is likely to influence market dynamics for a relatively long time in the future. Consequently, getting the process right is of utmost importance.

2.3. Monitor’s attempt to balance competition requirements and patients’ interest

It is in this general framework and with such dynamic considerations in mind that the specific guidance provided by Monitor on its interpretation and foreseen enforcement of Regulation 10 should be analysed. Generally, the balancing test proposed by Monitor can be described in the following terms:

*In assessing whether or not anti-competitive behaviour is in the interests of health care service users, Monitor will first **consider the impact of the behaviour on competition**. [Monitor] will assess whether the behaviour affects competition in a way that gives rise to an adverse effect for patients by **removing or materially reducing the incentives on providers** to provide high-quality services, provide value for money and/or improve services. If it does, [Monitor] will consider **whether it also gives rise to benefits** that could not be achieved without the restriction on competition. Monitor will then consider **whether any benefits outweigh any adverse effects** from the loss of competition in order to establish whether the behaviour is in the overall interests of patients.*²³

This is presented as a clearly qualitative approach to the balancing of competing interests or considerations in NHS commissioning and Monitor seems to have clearly departed from the apparently more precise and economic (*ie* financially-oriented) cost/benefit analysis that it had proposed in the draft substantive guidance published in May

²⁰ C Maxwell, Office of Fair Trading (OFT), “Competition in public services”, (above n 19), emphasis added.

²¹ OFT, *Annual Plan 2013-14*, available at <http://www.oft.gov.uk/about-the-oft/annual-plan-and-report/annual/> [Accessed July 8, 2014].

²² In the related area of private health care, the Competition and Markets Authority has recently published its final report on measures to increase competition in the private healthcare market, April 2, 2014, available at https://assets.digital.cabinet-office.gov.uk/media/533af065e5274a5660000023/Private_healthcare_main_report.pdf [Accessed July 8, 2014].

²³ *Monitor’s Substantive Guidance 2013* (above n 14) pp. 61-62, emphasis added.

2013.²⁴ In the earlier draft guidance, Monitor aimed at ‘costing’ the distortions of competition and ‘pricing’ the benefits created by the less than fully competitive procurement scenarios. Under the revised and more qualitative guidance, the negative impacts on competition will be assessed according to a rather standard competition appraisal. Such analysis will be concerned with i) the nature of the restriction on competition, ii) the number of providers of a particular health care service that are affected by the commissioner’s conduct and their importance as suppliers of that service, iii) the extent to which those providers affected by the conduct are close alternatives, and iv) the expected duration of the conduct or its effects. In this regard, the screening that Monitor intends to carry out to identify the negative effects of anti-competitive NHS commissioning broadly follows the accepted analytical methods of most non-sectoral competition authorities.²⁵ Hence, it should be expected that the negative effects identified under this methodology are mainly of an economic nature and primarily concerned with static and dynamic reduction of competition and, eventually, with an overall restriction of choice in case of exit of some of the suppliers from the given market.

However, the assessment of the benefits that may compensate for such negative implications of a restriction of competition in NHS procurement and commissioning creates some analytical difficulties. Those derive from the fact that Monitor will not exclusively focus on economic efficiencies, or even on efficiencies that can easily be translated into economic terms. As clearly spelled out

Monitor will also consider whether the behaviour gives rise to any material benefits to users of NHS health care services, such that the behaviour would be considered to be in the interests of health care service users.[...] Benefits can arise in a number of different ways. In addition to improvements in quality through co-operation and the delivery of care in an integrated way, benefits may arise as a result of improvements in efficiency that lead to better value for money. Behaviour may result in better value for money for a number of different reasons, for example, through a reduction in duplicated patient assessments, etc. Improvements in quality may consist of clinical or non-clinical improvements:

- ***clinical benefits** may include a variety of improvements that lead to better patient outcomes (for example, by increasing the number of patients treated by a provider where higher patient volumes result in better outcomes); and*
- ***non-clinical benefits** may include a range of improvements such as better patient experience, better access for patients (for example, longer and/or more convenient opening hours, improved surroundings or better amenities).²⁶*

Monitor will then assess those benefits taking into consideration their materiality, such as the relevance of the qualitative improvements and the number of patients that can benefit from them, their lead time (*ie* period necessary to achieve them) and duration, and the robustness of the analysis and evidence that supports them. It will also consider whether the restrictions on competition are actually necessary to achieve the benefits. More specifically, ‘Monitor will consider the extent to which achieving the benefits more quickly or cost-effectively outweighs the cost resulting from the reduction in competition as part of its cost/benefit analysis’.²⁷

This analytical framework creates uncertainty, as it revolves around qualitative elements that differ from the standard ‘efficiency analysis’ that competition authorities usually consider in their enforcement of competition rules and focuses on parameters that are difficult to define and to measure in an objective manner.²⁸ It may also be

²⁴ Indeed, the previous drafting of the same section of the substantive guidance was formulated in seemingly more financially-driven terms: ‘When will behaviour be anti-competitive and not in the interests of users of health care services? [...] In assessing whether or not anti-competitive behaviour is in the interests of health care service users, Monitor will carry out a cost/benefit analysis. Monitor will consider whether by preventing, restricting or distorting competition behaviour gives rise to material adverse effects (costs) for health care service users. If we find that behaviour gives rise to material costs, we will consider whether it also gives rise to benefits that could not be achieved without the restriction on competition. Monitor will then weigh the benefits and costs against each other’. For an indication of the reasons why Monitor has adopted more clearly a qualitative assessment framework, see Monitor, *Guidance on the Procurement, Patient Choice and Competition Regulations: consultation response*, pages 29-30, available at <http://www.monitor.gov.uk/sites/default/files/publications/ConsultationDec13.pdf> [Accessed July 8, 2014].

²⁵ E.g. see European Commission, *Guidelines on the applicability of Article 101 of the Treaty on the Functioning of the European Union to horizontal co-operation agreements* [2011] OJ C11/1.

²⁶ Monitor’s *Substantive Guidance 2013* (above n 14) p. 63.

²⁷ *Ibid.*

²⁸ See European Commission, *Guidelines on the application of Article [101(3)] of the Treaty* [2004] OJ C101/97. The guidelines treat qualitative efficiencies in paragraphs 69-72, where the approach clearly supports the taking into account of qualitative efficiencies related to technological development or increased choice. That seems to indicate that qualitative elements such as clinical outcomes may be more difficult to bring in line or consider covered by that guidance. Regarding the difficulties of taking into consideration qualitative efficiencies, see the note prepared by the European Commission to the OECD, *Roundtable on the Role and Measurement of Quality in Competition Analysis*, DAF/COMP/WD(2013)32, June 13, 2013, available at

sometimes difficult to justify the acceptability of a costly restriction of competition where the expected benefits may be diffuse or not rank very highly in terms of the priorities for the improvement in the provision of health care services. That will require Monitor to engage in regulatory and policy-led decision-making, which may lead to conflicts with its own competition law enforcement duties (see below §3). In the end, the methodology for the cost/benefit analysis (in both clinical and non-clinical dimensions) results in the consideration that

*This is not a mathematical exercise, but a qualitative assessment. Relevant benefits might outweigh the restriction on competition when, for example, as a result of a commissioner's actions there is a reduction of competition between a small number of providers, but a significant number of other providers of the relevant services remain and the clinical benefits of the initiative are significant and well evidenced.*²⁹

2.4. Monitor's disclosed enforcement strategy and its role as co-competent competition authority

This qualitative or "soft" approach to the balancing and trade-off of competition and other considerations in the patients' interest has been exemplified by a number of theoretical case studies published by Monitor to provide some more concrete indications as to the type of analysis to be carried out and considerations deemed pertinent.³⁰ This guidance is also complemented by other, more specific assessments concerned with the implications of competition rules for the delivery of integrated care³¹ and for agreements between providers of NHS-funded health care services.³² All of these soft law instruments provide a substantial amount of information and analytical leads as to how Monitor will conduct such a balancing test when assessing procurement behaviour under Regulation 10.³³

It is also important to note that Monitor plans to apply Regulation 10 in relatively exceptional circumstances.³⁴ Ultimately, Monitor considers that "patients' interest" is the overall driver for decision-making in NHS commissioning processes and, consequently, expects procurement decisions to comply with Regulation 10 if they comply with the rest of the *NHS Procurement, Patient Choice and Competition Regulations 2013*. By way of example, Monitor has indicated that it is unlikely to subject the following decisions to scrutiny under Regulation 10: i) those about whether to procure services by way of a competitive tendering process, ii) decisions about the number of providers with whom to enter into a contract, or iii) decisions concerned with treating providers equally during a procurement process.³⁵ The main justification for such exclusions is that those decisions will rather be assessed under more general rules, such as Regulation 2 on the objectives of NHS procurement, or the principle of non-discrimination. In my view, this creates rigidity in the system and opts for a formal review rather than a substantive assessment of the effects that certain decisions can generate in the markets concerned, which is criticisable.³⁶ More generally, Monitor has indicated that "Where a commissioner has taken a procurement decision in accordance with this framework, it is unlikely that conduct that flows from that decision would breach Regulation 10" and, consequently, that it "will review conduct under Regulation 10 where a commissioner has engaged in other (sic) types of behaviour that restricts competition that is not in patients' interests".³⁷

http://ec.europa.eu/competition/international/multilateral/2013_june_roundtable_quality_en.pdf [Accessed July 8, 2014]. For a general view considering that there is a broad array of goals and considerations that would be covered by Article 101(3) TFEU, *cfr* C Townley *Article 81 EC and Public Policy* (Oxford: Hart Publishing, 2009).

²⁹ *Monitor's Substantive Guidance 2013* (above n 14) p. 64, emphasis added.

³⁰ Monitor, *Hypothetical case scenarios: Procurement, Patient Choice and Competition Regulations*, December 2013, available at https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/283509/HypotheticalScenariosDec13.pdf [Accessed July 8, 2014].

³¹ Cooperation and Competition Panel (now, Monitor), *The Implications of Competition Rules for the Delivery of Integrated Care*, 14 December 2012, available at <http://www.nhsft-regulator.gov.uk/regulating-health-care-providers-commissioners/cooperation-and-competition/archive-co-operation-and--2> [Accessed July 8, 2014].

³² Cooperation and Competition Panel (now, Monitor), *The Implications of Competition Rules for Agreements Involving Providers of NHS-Funded Health care Services*, 22 March 2013, available at <http://www.nhsft-regulator.gov.uk/regulating-health-care-providers-commissioners/cooperation-and-competition/archive-co-operation-and--2> [Accessed July 8, 2014].

³³ In my view, the examples are concerned with scenarios in which the existence of a restriction of competition is itself doubtful (usually due to *de minimis* considerations) and, in any case, the guidance relies on the existence of very clear and immediately realisable qualitative gains derived from the apparently anti-competitive practice. As such, then, the guidance is mainly helpful for 'clear-cut' cases, but it does not dispel the doubts surrounding the analysis of more complicated situations, where a clear and significant restriction of competition arises in the first phase of the analysis and the qualitative justifications are not so clear either.

³⁴ Monitor, *Enforcement guidance on the Procurement, Patient Choice and Competition Regulations*, IRCP (R) 08/13, December 2013, available at <http://www.monitor.gov.uk/s75> [Accessed July 8, 2014].

³⁵ *Monitor's Substantive Guidance 2013* (above n 14) p. 67.

³⁶ For an elaborate criticism of such type of formal approaches, see A Sanchez-Graells, *Public Procurement and the EU Competition Rules* (Oxford: Hart Publishing, 2011), pp. 189-221.

³⁷ *Monitor's Substantive Guidance 2013* (above n 14) p. 66; see also the specific examples of such practices, which amount to very clear instances of exclusionary conduct or imposition of unnecessary competition-restrictive conditions, on p. 65.

At first sight, this generally lenient approach towards the strict interpretation and enforcement of Regulation 10 seems difficult to reconcile with the fact that Monitor is entrusted with a responsibility for enforcing rules on competition in the health care sector by the *Health and Social Care Act 2012*, concurrently with the Competition and Markets Authority.³⁸ More specifically, Section 62(3) of the *Health and Social Care Act 2012* requires that “*Monitor must exercise its functions with a view to preventing anti-competitive behaviour in the provision of health care services for the purposes of the NHS which is against the interests of people who use such services*” and Section 64(2) clarifies that “‘*Anti-competitive behaviour*’ means behaviour which would (or would be likely to) prevent, restrict or distort competition and a reference to preventing anti-competitive behaviour **includes a reference to eliminating or reducing the effects (or potential effects) of the behaviour**” (emphasis added).

Moreover, under Section 74 of the *Health and Social Care Act 2012*, Monitor is obliged to dismiss any of its duties as a sectoral regulator when it enforces competition provisions, except if they relate to issues that the Competition and Markets Authority could take into account if it was the acting competition authority.³⁹ A parallel provision on the avoidance of conflicts between the several duties to be carried out by Monitor can be found in Section 67, which clearly indicates that “*Monitor must ignore the functions it has under sections 111 and 113 [ie certain regulatory functions concerned with licensing] when exercising— (a) its functions under Chapter 2 (competition)*”. Therefore, given its configuration as the co-competent sectoral competition authority for health care markets by the *Health and Social Care Act 2012*,⁴⁰ it could be expected from Monitor to take a stronger approach to the enforcement of Regulation 10 of the *NHS Procurement, Patient Choice and Competition Regulations 2013*. Such a strong take on the protection of competition could also derive from Monitor’s obligations under EU competition law in certain cases (see below §3).

2.5. Preliminary assessment

All in all, given this indication of an exceptional (or lenient) approach towards the enforcement of Regulation 10 and given the very open-ended methodology described in *Monitor’s Substantive Guidance 2013*, the impression is that the analysis to be carried out by Monitor may err on the side of allowing NHS commissioners to engage in an excessive amount of anti-competitive behaviour, particularly in view of the potential relevance given to qualitative (and, hence, difficult to measure) benefits. Such a lenient approach, however, is not exactly matched when Monitor indicates the type of factors it will take into consideration when assessing whether a commissioner has engaged in disproportionate or unjustified anti-competitive behaviour, which include examples such as whether the commissioner: i) has prevented a provider from entering or caused it to exit the market, ii) has limited the extent to which existing providers are able to compete to attract patients, iii) has restricted the ability of existing providers to differentiate themselves to attract patients, or iv) has reduced the incentives on existing providers to compete (for example, by disclosing commercially sensitive information belonging to one provider to a different provider without objective justification).⁴¹

Therefore, it seems that the substantive guidance is strict in terms of promoting or not reducing competition between providers in their interface with patients, unless the cost/benefit analysis indicates a qualitative advantage for patients that derives from any restriction of competition. As indicated by Regulation 10(1), advantages such as vertical or horizontal integration of services, joint provision, or standardisation of conditions will be relevant. After reading the substantive guidance, however, it is not clear whether the structurally strict approach of Regulation 10(2) will restrict the “anti-competitive authorisation” of Regulation 10(1) or, on the contrary, if Regulation 10(2) will also be affected by the “qualitative” approach of Regulation 10(1).

In light of all the previous considerations regarding the scope, interpretation and likely enforcement of Regulation 10 of the *NHS Procurement, Patient Choice and Competition Regulations 2013* by the sectoral regulator Monitor, the following two sections critically assess its compatibility with EU economic law and, more specifically, with EU competition law (§3) and EU public procurement law (§4).

3. Compatibility of Regulation 10 with EU competition law

Before engaging in more detailed discussions concerning the compatibility of Regulation 10 of the *NHS Procurement, Patient Choice and Competition Regulations 2013* with EU competition law, it might be worth stressing that all the guidance provided by Monitor, including in relation to its enforcement priorities (above §2), “*does not cover Monitor’s use of its other enforcement powers, such as [...] powers under the Competition Act*

³⁸ Monitor, *Enforcement Guidance* (above n 34) p. 11.

³⁹ *ie*, Monitor should apply competition rules as they would be applied by the ‘general’ competition authority.

⁴⁰ See Annex in ‘Monitor’s powers of enforcement under the Health and Social Care Act 2012’ in Monitor, *Enforcement Guidance* (above n 34).

⁴¹ *Monitor’s Substantive Guidance 2013* (above n 14) p. 65.

1998 and/or the Treaty on the Functioning of the European Union”.⁴² Therefore, Monitor seems to assume that the interpretation of Regulation 10 can be severed and somehow isolated from the *corpus* of EU competition rules. Such a seemingly separate approach to the enforcement of competition-based legal rules may trigger issues of compatibility of the specific guidance on the enforcement of Regulation 10 of the *NHS Procurement, Patient Choice and Competition Regulations 2013* and EU competition rules in Articles 101 and 102 TFEU, particularly as further specified in Regulation 1/2003.⁴³

Such issues may pose particular difficulties to Monitor in the application of Regulation 10 of the *NHS Procurement, Patient Choice and Competition Regulations 2013* were it to opt for a more lenient approach than that called for under general competition rules and procedures. As Monitor itself has clearly indicated, “when Monitor takes action under the Competition Act, we must adhere to the same statutory rules that the OFT [now the Competition and Markets Authority] would if it were taking the case [...] Similarly, when enforcing Articles 101 and 102 of the TFEU, Monitor must comply with the requirements in European Union Regulation 1/2003”.⁴⁴ It can be argued that this means that Monitor, being a concurrently competent competition authority empowered to act *ex officio* in competition law cases,⁴⁵ should always comply with the same enforcement obligations, priorities and (equivalent) procedures as the other concurrent authority (the Competition and Markets Authority). Hence, Monitor should not be allowed to treat potential restrictions of competition more leniently or strictly under Regulation 10 than under ‘general’ competition rules.

If such a premise is accepted, it is then necessary to clarify to what extent can Monitor take into consideration ‘qualitative efficiencies’ (*ie* non-economic or medical/clinical aspects of the concept of “patients’ interest”) within the framework provided by the relevant EU competition rules. That is, to assess how far it can push the ‘not mathematical exercise, but qualitative assessment’ test that enforcing Regulation 10 ultimately requires (above §2). Before engaging in that discussion, it is important to acknowledge that a potential conflict of substantive assessments will only arise where EU competition law is applicable,⁴⁶ which triggers the question of whether a cross-border competition effect needs to exist for EU law to be relevant. However, given the relatively unclear state of the law on the territorial boundaries of EU competition law,⁴⁷ it is submitted that clashing substantive assessments should be avoided as a matter of *bona fide* compliance with Article 3(2) of Regulation 1/2003.⁴⁸ Moreover, such harmonisation of substantive assessment would increase legal certainty, since undertakings would know that they are bound to be subjected to the same rules regardless of any eventual final finding on the existence (or not) of a cross-border distortion of competition.

In that regard, it is important to stress that under paragraphs 69 to 72 of the *Guidelines on the application of Article [101(3)] of the Treaty*, the European Commission has indicated that the ‘qualitative efficiencies’ it is willing to take into account as a justification for an otherwise anti-competitive agreement are primarily concerned with research and development efforts (para 70) leading to: i) the offer of new or improved goods and services, or ii) products and services of higher quality or with novel features (para 71), or iii) services that are better tailored to customer needs or iv) to provide quicker delivery or better quality assurance (para 72). In that regard, it seems possible to reconcile “patients’ interest” understood as significant qualitative clinical and non-clinical advantages (above §2) with the type of qualitative efficiency that the European Commission would in principle be willing to take into account.⁴⁹

When it comes to the assessment of the degree to which those efficiencies are passed on to the final users, it is also relevant to take into account that the *Guidelines on the application of Article [101(3)] of the Treaty* also acknowledge that “Any such assessment **necessarily requires value judgment**. It is difficult to assign precise values

⁴² Monitor, *Enforcement Guidance* (above n 34). For general discussion, see S Pibworth “Enforcement of Competition Law in the UK Health care Sector” (2013) *Competition Law Journal* 87.

⁴³ Council Regulation (EC) No 1/2003 of 16 December 2002 on the implementation of the rules on competition laid down in Articles [101] and [102] of the Treaty, OJ [2003] L 1/1.

⁴⁴ Monitor, *Enforcement Guidance* (above n 38) p. 39.

⁴⁵ Including potential breaches of Regulation 10.

⁴⁶ *ie*, where there is a “prevention, restriction or distortion of competition within the internal market”.

⁴⁷ And, more generally, of EU economic law related to the internal market fundamental freedoms. For an interesting discussion, see P Caro de Sousa “Catch Me If You Can? The Market Freedoms’ Ever-expanding Outer Limits” (2011) 4(2) *European Journal of Legal Studies* 162.

⁴⁸ Which *de facto* imposes substantive harmonisation of non-unilateral anti-competitive behaviour, at least where there is scope for the joint application of EU and domestic competition rules. On the impact of Regulation 1/2003 on the substantive competition rules of the Member States, see K Cseres “Comparing Laws in the Enforcement of EU and National Competition Laws” (2010) 3(1) *European Journal of Legal Studies* 7. For a more critical approach to the harmonisation process, K Ceres “Questions of Legitimacy in the Europeanization of Competition Law Procedures of the EU Member States” (2013) *Amsterdam Centre for European Law and Governance Working Paper Series 2013–02*, available at <http://acelg.uva.nl/publications> [Accessed July 8, 2014].

⁴⁹ Always provided that they are demonstrated to exist to the required standard of proof.

to dynamic efficiencies of this nature. However, the fundamental objective of the assessment remains the same, namely to ascertain the overall impact of the agreement on the consumers within the relevant market” (para 103, emphasis added). Additional informal guidance provided by the Commission strengthens this point by acknowledging that “*The assessment of quality is thus often a complex and imprecise exercise in itself, and involves the balancing of evidence which is often of subjective nature such as different perception of customers*”,⁵⁰ or that “*The possibility to use more exact quantitative tools is – contrary to an assessment focused on prices – more limited*”.⁵¹ A similar approach is followed by the OFT in the assessment of qualitative efficiencies that create direct economic benefits and to the inclusion of non-economic efficiencies under Article 101(3) TFEU analysis.⁵²

Therefore, the general approach anticipated by Monitor⁵³ seems fundamentally aligned with the approach indicated by the European Commission and the concurrently competent UK authority, although the ultimate way in which the value judgment is achieved may differ.⁵⁴ In this regard, it will be important for Monitor to be very strict in the assessment of the perceived efficiencies (or, rather, of the efficiencies claimed by the NHS commissioners engaged in anti-competitive procurement in the patients’ interest), given that the European Commission does subject qualitative efficiencies to strict evidentiary requirements.

In this regard, it is worth emphasizing that, despite the general acceptability of such efficiencies, “*the Commission will not simply accept quality improvement claims without further assessment. Parties that successfully want to rely on such claims must substantiate them in a way that allows the Commission to verify, inter alia, the causal link between the agreement and the quality improvements; their likelihood and magnitude; how and when the quality improvements would be achieved. To this end, the parties must bring forward convincing arguments and evidence*”.⁵⁵ Therefore, in order to avoid breaching EU competition law, Monitor should keep a demanding approach towards the assessment of non-competitive dimension of “patients’ interest” in the application of Regulation 10 of the *NHS Procurement, Patient Choice and Competition Regulations 2013*. A similarly strict approach will be required under EU public procurement law, as the following section shows.

4. Compatibility of Regulation 10 with EU public procurement law

As mentioned in passing (above §1), Regulation 10 and the potential for NHS commissioners to engage in less than competitive tendering and contracting on the basis of “patient’s interest” raise a *prima facie* case of incompatibility with EU public procurement law and, more specifically, with the goal and principle of competition thereby embedded. As formulated in Article 18 of Directive 2014/24, it is a general principle of EU procurement law that it has to run in a way that avoids distortions or restrictions of competition; and, more precisely,

The design of the procurement shall not be made with the intention [...] of artificially narrowing competition. Competition shall be considered to be artificially narrowed where the design of the procurement is made with the intention of unduly favouring or disadvantaging certain economic operators (emphasis added).

Given that Regulation 10 of the *NHS Procurement, Patient Choice and Competition Regulations 2013* precisely creates a justification for anti-competitive commissioning or procurement in the “patients’ interest”, at least as a matter of principle, there seems to be scope for a clash between these two rules. In this regard, it seems relevant to stress that Monitor seems to have taken a different general view on this point of compatibility, as it has clearly indicated that compliance with the “*requirements in the Procurement, Patient Choice and Competition Regulations create a framework for decision making that will assist commissioners to comply with [...] other legislative requirements [that] include: [...] the Public Contracts Regulations 2006, the Public Sector Directive (Directive 2004/18/EC) and general European Union (EU) law*”.⁵⁶

This section explores to what extent Regulation 10 (under the scope and interpretation analysed above §2) can actually be considered compatible with the general requirements of the EU public procurement rules and, more

⁵⁰ *Role and Measurement of Quality in Competition Analysis* (above n 28) para. 10, emphasis added.

⁵¹ *Ibid.*, para. 12, emphasis added.

⁵² OFT, *ARTICLE 101(3) – A Discussion of Narrow Versus Broad Definition of Benefits*, 2010, available at [http://www.oft.gov.uk/shared_of/events/Article101\(3\)-summary.pdf](http://www.oft.gov.uk/shared_of/events/Article101(3)-summary.pdf) [Accessed July 8, 2014].

⁵³ ‘*This is not a mathematical exercise, but a qualitative assessment*’.

⁵⁴ The differences can be derived from Monitor’s already discussed potential bias towards a lenient or soft approach in the enforcement of Regulation 10, which should be countervailed by its obligations not to take into account regulatory powers and discretion when enforcing competition rules (above §2).

⁵⁵ *Role and Measurement of Quality in Competition Analysis* (above n 28) para. 25.

⁵⁶ *Monitor’s Substantive Guidance 2013* (above n 14) p. 8. There is no indication that Monitor has a different view where the new Directive 2014/24 is concerned.

specifically, of the general principle of competition. It is worth stressing that, in the remainder of the paper, the new public procurement Directive will be used as an indication of the applicable EU public procurement law (despite it not being yet directly effective and its transposition not being due before April 2016). Not least, the comment on the new Directive is justified because Article 76 complements Article 18 and includes a special regime for social services (including health care services) that introduces an additional but separate, more specific set of principles for the award of those contracts.

Indeed, under a new light-touch regime, health care contracts included in Annex XIV⁵⁷ and of a value above the financial thresholds defined in Article 4(d) of the new Directive⁵⁸ will be subjected to the special award procedures regulated in Articles 74 to 77 of Directive 2014/24. For the purposes of this analysis, it is important to stress that, without necessarily derogating Article 18, Article 76 of the new Directive introduces a specific set of additional special principles to be taken into account in the award of social services contracts, including health care contracts. Article 76(1) expressly requires that the domestic rules transposing the Directive ensure that contracting authorities comply with the principles of transparency and equal treatment of economic operators. Moreover, according to Article 76(2) of the new Directive,

Member States shall ensure that contracting authorities may take into account the need to ensure quality, continuity, accessibility, affordability, availability and comprehensiveness of the services, the specific needs of different categories of users, including disadvantaged and vulnerable groups, the involvement and empowerment of users and innovation. Member States may also provide that the choice of the service provider shall be made on the basis of the tender presenting the best price-quality ratio, taking into account quality and sustainability criteria for social services.

Overall, there seems to be nothing in Article 76 that deactivates the requirement in Article 18 that procurement for social services, including health care, shall be conducted without the intention of artificially narrowing competition. Or, in more natural terms, that such procurement is conducted in at least a competition-neutral manner. It also seems to be lacking any specific rule that would deactivate the presumption that competition shall be considered to have been artificially narrowed where the design of the procurement is made with the intention of unduly favouring or disadvantaging certain economic operators. The fact that Article 76(1) only expressly mentions the principles of transparency and equal treatment (so that, *a contrario*, there could be a deviation from the requirement for competition) seems unsatisfactory as a reason to exclude pro-competitive requirements. Consequently, the proposed interpretation of the specific criteria listed in Article 76(2) of the new Directive is that they still need to be identified and implemented in a manner that falls short from introducing unjustified restrictions or distortions of competition.

If that general approach is correct, then, even if it could be understood that the standard of “patients’ interest” in Regulation 10 of the *NHS Procurement, Patient Choice and Competition Regulations 2013* is the domestic equivalent of the “quality-related” elements in Article 76(2) of the new procurement Directive,⁵⁹ the authorisation of anti-competitive procurement still seems to fall outside the increased scope for flexibility created in Directive 2014/24 for the procurement of social services. This is so, at least, as a matter of a general authorisation to completely exclude competition in the tendering of those contracts. Indeed, even in the most extreme deviation from the general system based in undistorted competition for public contracts that the new Directive allows for in the area of social services—*ie* the possibility to reserve contracts for certain services to certain types of organisation (Article 77)—there is still a requirement to compete the contract and direct awards are forbidden. Consequently, even taking into account all the flexibility and leeway created in the special regime for the award of social and other specific services of the new Directive, EU public procurement rules are at odds with a general authorisation for anti-competitive procurement in the patients’ interest that could be read in Regulation 10 of the *NHS Procurement, Patient Choice and Competition Regulations 2013*.

It is submitted that such an incompatibility is rightly created by the Directive because, even in cases where there are particular patients’ needs, and after such needs have been identified (and translated into technical specifications and contractual requirements, competition between all providers potentially able to satisfy them is the only way of ensuring that, ultimately, there is an actual delivery of the services or goods necessary to satisfy that need to the highest possible quality level. In other words, NHS commissioners can specify as demanding requirements as they consider appropriate and proportionate to satisfy the perceived patients’ needs—but, once they have done so, they must refrain from engaging in any artificial restriction of the competition for the award for the contract (under those demanding criteria). Consequently, from the procurement perspective, any reduction of competition for the contract

⁵⁷ Annex XIV covers virtually all health care related activities.

⁵⁸ 750,000 Euro; currently approximately 600,000 GBP.

⁵⁹ Particularly in terms of the needs of different categories of vulnerable users, such as patients requiring long-term or intense care.

that does not stem from an objectively verifiable need⁶⁰ should be deemed an artificial restriction of competition that would be in breach of Articles 18 and 76 of the new public procurement Directive.

Indeed, it should not be overseen that according to Monitor itself, “*Competition [...] to obtain contracts to provide services can incentivise providers to improve both the quality of the services they provide and value for money. Competition can therefore give rise to a range of benefits for users of health care services, including improved clinical outcomes, safer health care and a better patient experience (as a result of, for example, better amenities and surroundings or through care being delivered in a more integrated way with other services)*”.⁶¹ Therefore, the potential conflict between patients’ interests and badly-designed competition for the provision of services should not be sorted out by excluding competition. The reconciliation of these competing goals should rather derive from improved procurement techniques that are better suited to the proper identification of the patients’ needs and their translation into technical specifications and contractual requirements, or contract compliance clauses. To be sure, the distinction between necessary and unnecessary procurement requirements will be difficult and may entail certain value judgments, but this is in line with the ‘competition-dimension’ of the enforcement of Regulation 10 and, consequently, should be subjected to equally demanding standards of evidence (above §3).

From a purely technical perspective, then, it is submitted that Regulation 10 of the *NHS Procurement, Patient Choice and Competition Regulations 2013* can only be reconciled with the general requirements of the principle of competition consolidated in Article 18 of Directive 2014/24 and the specific criteria of Article 76(2) of the same Directive for the procurement of social services if NHS commissioners can discharge a demanding standard of proof in justifying that: i) the inclusion of any qualitative requirements in the “patients’ interest” that imply a reduction of potential competition for the contract is clearly and soundly justified from the perspective of the clinical/medical needs to be satisfied; and ii) no potential supplier that could have satisfied those needs has been artificially excluded from the tendering/award process. Otherwise, at least for contracts covered by Directive 2014/24,⁶² Regulation 10 of the *NHS Procurement, Patient Choice and Competition Regulations 2013* would not provide a justification compliant with EU law and anti-competitive public procurement⁶³ would be in breach of EU public procurement law, regardless of it being considered justified on the basis of the standard of “patients’ interest” created under the *NHS Procurement, Patient Choice and Competition Regulations 2013*.

It is submitted that the same conclusion will apply to contracts under the EU value threshold, given the long standing CJEU case law that extends the requirements of the general principles of EU public procurement law⁶⁴ to contracts not or not fully covered by the Directives.⁶⁵ However, there may be more room for discussion and some further clarification, *eg* via references for a preliminary ruling under Article 267 TFEU, may be necessary in this area before reaching a final conclusion.

5. Conclusion

This paper has assessed the compatibility of Regulation 10 of the *NHS Procurement, Patient Choice and Competition Regulations 2013* with EU competition and public procurement law. Regardless of that Regulation’s open-ended drafting authorizing “anti-competitive procurement in the patients’ interest”, the requirements of EU competition and public procurement law impose a restrictive interpretation that closely scrutinizes the existence of demonstrable and relevant (non-economic) qualitative efficiencies that justify any potential restriction of competition. Therefore, the initial substantive guidance provided by Monitor on the interpretation and enforcement of Regulation 10—which indicates a lenient approach leading towards a possible authorization of an excessive amount of anti-competitive conduct—may need to be adjusted to comply with the highest standards of scrutiny imposed by EU competition and public procurement law.

Hence, there is no fundamental inconsistency between Regulation 10 and EU economic law, but its enforcement needs to remain within the strict evidentiary rules governing a trade-off between economic efficiency and qualitative improvement in the provision of services. Monitor also needs to avoid giving excessive weight to considerations linked to its regulatory role when making the value judgments implicit in the review of anti-competitive procurement decisions where there is a claim of justification in the patients’ interest.

⁶⁰ Or, in other words, any imposition of a requirement that is not necessary to achieve the ‘qualitative efficiencies’ that would justify the practice from a strict competition law perspective; see above §3.

⁶¹ *Monitor’s Substantive Guidance 2013* (above n 14) p. 31.

⁶² *ie* health care contracts included in Annex XIV with a value above 750,000 Euro or 600,000 GBP.

⁶³ *ie* procurement that artificially narrowed down competition and, particularly, as a result of a design made with the intention of unduly favouring or disadvantaging certain economic operators, such as the incumbent providers of health care services.

⁶⁴ Now clearly including the principle of competition.

⁶⁵ Generally, C Risvig Hansen *Contracts not covered or not fully covered by the Public Sector Directive* (Copenhagen: DJØF, 2012). See also BJ Drijber and H Stergiou, “Public procurement law and internal market law” (2009) 46(3) *C.M.L.Rev* 805.